

REMARKS

Claims 29-43 are rejected. Claims 29, and 37-40 have been amended. Claims 35 and 36 have been canceled. Claims 29-34, 37-43 are presently pending in the application. Favorable reconsideration of the application in view of the following remarks is respectfully requested.

The basis for the amendment of claim 29 is found in claims 35 and 36 as originally filed. The basis for the amendment of claims 37-40 is found in the dependency of those same claims as originally filed.

Rejection Of Claims 29-43 Under 35 U.S.C. §103(a):

The Examiner has Claims 29-43 under 35 U.S.C. §103(a) as being unpatentable over Sutton et al. in view of Pierce et al. for the reasons as stated in the last office action and Applicant's arguments are based on the claimed characteristics in that the vinylsulfonyl functionalized polymer is soluble in water, water miscible solvents, or a mixture thereof, which depend on the function of the groups attached to said polymer in that only a vinylsulfonyl group has been claimed and the claims are broad enough to include any polymer having a vinylsulfonyl group should have the claimed characteristics and the references do disclose the claimed polymer.

Sutton discloses a water-insoluble polymeric particle has an inner core comprising a detectable tracer material distributed in a first polymer for which the tracer material has a high affinity and an outer shell comprising a second polymer for which the tracer material has substantially less affinity relative to said first polymer. This second polymer contains groups which are either reactive with free amino or sulphydryl groups of an immunoreactive species or which can be activated for reaction with such groups. Such a species can be covalently attached to this particle to form an immunoreactive reagent which is useful in analytical elements and various analytical methods including immunological methods, for example, agglutination assays. This invention relates to a core/shell polymer particle containing a detectable tracer material in the core only.

Pierce discloses an element for the analysis or transport of liquid, especially aqueous liquids, containing a structure comprising a plurality of heat-stable, organo-polymeric particles non-swellable in and impermeable to the liquid, and an adhesive concentrated at particle surface areas contiguous to

adjacent particles bonding the particles into a coherent, three-dimensional lattice that is non-swellable in the liquid. These structures are particularly useful in the "dry chemistry" analysis of aqueous liquids. "Dry chemistry" analysis refers to analytical methods and techniques that are carried out using chemical reagents contained in various "dry-to-the-touch" test elements such as "dip-and-read" test strips, multilayer test elements and the like.

The present invention relates to a polymer particle comprising a monodispersed polymer bead stabilized by vinylsulfonyl-functionalized polymers, which are soluble in water, water-miscible solvents, or a mixture thereof, grafted to the surface of the bead, which are useful in a biological assay to allow a biological capture agent to be easily attached to the surface of such microspheres without using any chemical coupling agents and which allow the tag to retain higher reactivity than the same compounds bound directly to the surface of a similar bead. These particles are stable and dispersible in aqueous systems (pg. 6, lines 22-27) and, as indicated in the specification on pg. 3, lines 17-25, demonstrate enhanced reactivity of the immobilized target material.

To establish a *prima facia* case of obviousness requires, first, there must be some suggestion or motivation, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure. *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998).

The reference to Sutton fails to teach the modification required by the present invention, that is, the monodispersed particles of the present invention and monodispersed polymer beads stabilized by vinylsulfonyl-functionalized polymers, which are soluble in water, water-miscible solvents, or a mixture thereof, grafted to the surface of the bead, which are stable and dispersible in aqueous systems (pg. 6, lines 22-27) and, as indicated in the specification on pg. 3, lines 17-25, demonstrate enhanced reactivity of the immobilized target material. Pierce discloses a plurality of heat-stable, organo-polymeric particles non-swellable in and impermeable to the liquid for use in "dry chemistry"

applications, not polymer particles that are stabilized by water soluble vinylsulfonyl-functionalized polymers. At best, the combination of the references would produce a water-insoluble particle, while the present particle, as a result of the grafted vinylsulfonyl-functionalized polymers, which are soluble in water, water-miscible solvents, or a mixture thereof, are stable in aqueous suspension. (pg. 18, line 1, Example 5, pg. 22, using a suspension of the inventive particles, and Example 6, pg. 23, using a solution of the inventive particles)

The reference also fails to provide any likelihood of success, as there is no teaching to suggest the preparation of monodisperse particles useful in aqueous systems. Pierce and Sutton, as discussed above both teach water insoluble particles. The presently claimed particles, as a result of the presence of the grafted vinylsulfonyl-functionalized polymers, which are soluble in water, water-miscible solvents, or a mixture thereof, are stable in aqueous suspension. Pierce teaches the use of the particles in "dry chemistry" systems (col. 1, lines 8-15). Sutton specifically indicates the particles are water-insoluble (Abstract). Neither reference provides any likelihood of success in producing a water compatible particle for use in aqueous solution.

The references also fail to include all of the present claim limitations, since neither reference discloses or suggests grafted vinylsulfonyl-functionalized polymers, which are soluble in water, water-miscible solvents, or a mixture thereof, to produce particles that are stable in aqueous suspension.

The present invention provides surprising results, in that the presently claimed vinylsulfonyl-functionalized polymers are water dispersible or soluble. Example 5, pg. 22 lines 23-25, indicates the particles were suspended and remained suspended for 1 hour. ("The particles were resuspended in 2mg/mL of goat anti-mouse IgG in 0.1 M sodium phosphate buffer pH 7.0. The reaction was allowed to proceed for 1 hour at room temperature."). Example 6 , pg. 23, line 2, indicates the particles were soluble. ("a solution of 500 μ L of particles 1"). Sutton and Pierce teach insoluble particles.

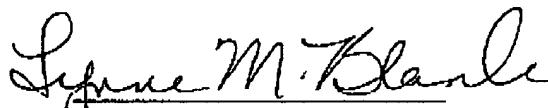
The Examiner indicates that Applicant's arguments are, based on the teachings from the specification on page 3, lines 17-25 to disclose said polymer, which states "*Macromolecular Rapid Communications Vol. 15 p. 909-915 (1994) reports the immobilization of enzymes to soluble stabilizer polymer arms protruding from the surface of a polymer particle. Enhancements in*

accessibility of the enzyme to target substrates are observed over enzymes covalently bound directly to the particle surface. However, the enzyme was reversibly adsorbed to the stabilizer arms and was not covalently bound. In addition, the stabilizer arms contained only carboxylic acids as their reactive functionality, so if covalent attachment was desired, it would require the use of a coupling agent and a subsequent preparative step.”, are not persuasive since they are not commensurate in scope with the claims. The present claims agree with this description. In the present invention, the enzymes are immobilized on the soluble stabilizer polymer arms (the present stabilizing polymer), which stabilizing polymer is protruding from the surface of the polymer particle. The enzymes are not bound directly to the particle surface, but are associated with the particle through attachment to the stabilizing polymer. Thus, the enhancements in accessibility of the enzyme to target substrates are observed through the attachment to the soluble stabilizing polymer, as opposed to the particle itself. In addition, the enzyme can be bound the stabilizing polymer without the use of a coupling agent and a subsequent preparative step. See pg. 7, lines 5-10.

In summary, the references fail to disclose, teach or suggest the present invention wherein a vinylsulfonyl-functionalized polymer, which is soluble in water, water-miscible solvents, or a mixture thereof, is grafted to the surface of the monodispersed polymer bead, fail to provide any likelihood of success for the use of monodispersed beads which are stabilized by a vinylsulfonyl-functionalized polymer, which is soluble in water, water-miscible solvents, or a mixture thereof, is grafted to the surface of the monodispersed polymer bead, resulting in the stability and dispersibility of these grafted polymer particle in aqueous systems, and fails to include the limitation that the polymer beads include a vinylsulfonyl-functionalized polymer, which is soluble in water, water-miscible solvents, or a mixture thereof, grafted to the surface of the monodispersed polymer bead. The Applicants therefore request that the Examiner reconsider and withdraw the rejection.

It is believed that the foregoing is a complete response to the Office Action and that the claims are in condition for allowance. Favorable reconsideration and early passage to issue is therefore earnestly solicited. Applicants respectfully request that this amendment be admitted in order to present the rejected claims in better form for consideration on appeal.

Respectfully submitted,



Attorney for Applicant(s)
Registration No. 42,334

Lynne M. Blank/ct

Rochester, NY 14650

Telephone: 585-477-7418

Faxsimile: 585-477-1148

If the Examiner is unable to reach the Applicant(s) Attorney at the telephone number provided, the Examiner is requested to communicate with Eastman Kodak Company Patent Operations at (585) 477-4656.